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Should be a patent law the platform where the moral questions are resolved?

List of abbreviations

Biotechnology Directive - Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions
ECHR - European Court of Human Right
EPO - European Patent Office
ESC - embryonic stem cells
EU – European Union
EU Charter - Charter of Fundamental Rights Of The European Union
TFEU – Treaty on Functioning of European Union
The Court of Justice – The Court of Justice of the European Union

Introduction

Bearing in mind the complexity of question of research on embryonic stem cells, we decided to devote this essay to one specific problem arising out of it, namely to the patentability of techniques connected with the research. We pose a question, whether patent law should create the platform, where the moral questions arising out of the biotechnology research are being solved.

Therefore it shall be stressed that the aim of this paper is neither to examine the morality of the research on ESC as such nor shall it tackle the relationship of morality and law.

We argue that **even though the moral questions are in a way interconnected with the patent law, the patentability should be excluded on the grounds of morality only in the very exceptional cases. And those are the situations, when the protected aim cannot be achieved by other tools which were directly created with the purpose of regulating the acceptability of relevant action.**

However we do not claim that the possible consequences of the ban on patentability of the techniques causing the destruction of an embryo, would not have a positive effect on the society. What we defend is that the situation, when the research on ESC as such is allowed in the majority of countries and at the same time it is practically impossible to grant a patent on result of the same research, is not desirable. If we want to claim, that the research is not in accordance with the principles of morality, we should ban the research as such. Using the patent law as a tool, we might manage to send a warning message into the society, that destroying of embryos on behalf of the science is not moral. But in this way one will never reach a clear and consistent answer to this peculiar question, neither in the form of NO nor YES.

Brüstle case, patent law and provisions on morality in its systematic

The incentive for choosing this topic was the case *Oliver Brüstle v. Greenpeace eV* on which the Court of Justice gave the judgement on 18th October 2011.[1] It was decided that techniques causing the destruction of an embryo are not patentable under the union law and that any human ovum after fertilisation constitutes a human embryo.

This judgment launched a vivid discussion on both sides of the public about the morality of research on ESC but apart from that it might have made some people think about the *purpose of patent law as such.*

To put it simply "a patent is a *limited monopoly right* granted in return for the disclosure of technical information" and it is acquired through an onerous application and grant procedure of significant cost. This burden is however worth of suffering, because the rights accompanying successful patent grant are seen as the strongest, and most valuable, of all intellectual property rights.[2]
In many countries patents represented the *very first steps towards the industrialized society*. Lot of countries took the concept of patents as a means how to *attract investments* from abroad in order to give an incentive to the industry on the national or local level.[3] Nowadays is the main rational for patenting for the most of the researchers the same, to attract of investments, even though the

[1] C-34/10 Oliver Brüstle v. Greenpeace eV
[2] Cf. BENTLY, Lionel a SHERMAN, Brad,.p. 337.
[3] Cf. . PILA, Justine:, p. 13-14.

system alone has changed. As Abraham Lincoln once said, patents provide the "fuel of interest to the fire of genius".

Prior to the advent of biotechnology industry the process of granting the patent right could be described in few simple steps.[4] As soon as invention met the conditions of being novel, containing an inventive step, and being capable of industrial application, then a patent monopoly might have been granted. When the biotechnology revolution broke out, European law was forced to leave this simple mechanism and to step out on an unsecure field of moral considerations. The debate about the overstepping of limits of morality by scientific research started to be reflected in legal debates alike. This process was launched by *biotechnology opponents* who risen their voices and started to invoke historical provisions within European patent law, that had been only rarely used before,[5] *banning patenting of inventions opposing the morality*. These provisions steamed from the trials not to grant the patent protection to inventions that would undermine morality or that would support behaviour against society and at the same time the protection of society could not be reached by other means.[6]

Case law on morality in the patent law

European Patent Office (EPO) had already dealt with the similar case prior to Brüstle and by its case law it established *the trend of restrictive interpretation of exclusion of patentability on the grounds of morality*.[7] It was extremely reluctant to make use of this provisions and it *sought not to be involved in the moral considerations* arising thereof. It even expressed the opinion that the national regulatory bodies shall be the right authorities for rendering judgements on morality of the research.

In this regard it might be more than suitable to mention the statements of declarations of the Examining Division and Opposition Division that literally doubted the European Patent Office as an appropriate forum in which to assess such ethical issues.[8] Following the same line of argumentation the EPO let himself heard later on that it should not be routinely involved in ethical considerations unless an invention would be universally regarded as outrageous and there existed overwhelming consensus that no patent should be granted".[9] It also argued in the way that "patent law and the patent system were *primarily* concerned with *technical considerations*, and should not be the forum in which ethical or moral opinions should play a role."[10]

After adoption of Biotechnology Directive there was the *change in approach* and instead of rather restrictive the interpretation begun to lean *towards extensive*[11] [12] *and literal way of interpretation* of the list of exhaustive exceptions of patentability.[13]

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[4] MILLS, Oliver, p. 2.
[5] Cf. BENTLY, Lionel a SHERMAN, p. 453.
[6] Cf. APLIN Tanya a DAVIS Jennifer, p. 453.
[7] Cases: T-19/90 *HARVARD/Onco-mouse* [1990] EPOR 501, 503; T-356/PLANT GENETIC SYSTEMS/Glutamine SynthetaseInhibitors 95 [1995] E.P.O.R. 357; T-272/95 HOWARD FLOREY/Relaxin [1995] E.P.O.R. 541.
[8] Cf. T-19/90 HARVARD/Onco-mouse [1990] EPOR 501, 513, par. 10.3.
[9] The Opposition Division, T-356/PLANT GENETIC SYSTEMS/Glutamine SynthetaseInhibitors 95 [1995] E.P.O.R
[10] Cf. BENTLY, Lionel a SHERMAN, p. 456.
[11] Cf. GUMMER, Thomas
[12] Eg cases T-1374/04 Wisconsin Alumni Research Foundation (WARF) [2009] EPOR 15, European patent 0 695 351 ("the Edinburgh patent")
[13] Eg. In the case of Edinbourg patent Board of Appeal came to the conclusion that there was no ethical objection which would be against patentability of processes connected with research on ESC regardless of their origin

The consequences of a judgement

The obvious and *inevitable consequence* of a judgement is that in all Member States of EU the *patents on techniques causing destruction of an embryo will not be granted*. And this will be the case even if these techniques are solely for scientific purposes or if the technical description in an application does not directly mention information about the necessity of the destruction of an embryo.[14] It is a matter of a personal opinion on morality of the research on ECS whether this fact is to be welcomed or not. It should be however stressed that the legality of the research on ECB in Member States of EU as such *will not be anyhow directly influenced* by the decision.
Its legality can be nevertheless *influenced indirectly*, most of all by removing the economical incentive for investors. This could be, and often is, an argument for prolife activists ascertaining that it is right when relevant techniques are banned on the grounds of provisions of patent law. They claim that the research will be cut out of its financial resources and in this way it will fade. We would not however dare to say so. As for example Chris Mason[15], an internationally recognised leader in stem cell science, once declared to this point, "I am unaware of a single project that has been cancelled or suspended as a result of this decision, or the WARF decision in 2008 for that matter".[16] Companies will also be for example able to rely on confidentiality rather than the patent system to protect techniques developed in this area of research.[17]

Despite the fact that the Brüstle judgment applies merely on Biotechnology directive, when it is read in the context of the related legal documents on the European[18] or international level[19], it turns out to be of high probability, that it can influence the *status and the level of legal protection of embryos*.

For instance it could change the way how the human dignity is perceived within the *Oviedo Convention Human Rights and Bio-medicine*.[20] If we are to use the definition of human dignity as defined by the ECJ in Brüstle and apply it to the Oviedo Convention, which is binding on all EU Member States, the implications would be massive—both within the realm of scientific research and also in the context of artificial procreation.[21]

Moreover Brüstle is the very first judgment on an intergovernmental level which sets forth that the life shall be protected from its beginning. It may happen that this approach will enshrine in the interpretation of the definition of human dignity under Art.1 of the *EU Charter*, which creates since Lisbon Treaty an integral part of the union law. And as the Court of Justice repeatedly reminds, the EU law shall be interpreted in the context and bearing in mind its complexity.[22]
Furthermore one shall not omit the role of European Court of Human Right in Strasbourg and the *European Convention on Human Rights and Fundamental Freedoms* when it deals with the questions of human dignity. Before the Brüstle judgment there was a case pending before ECHR where the question of when the human life begins appeared. ECHR stated that "the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere."[23] Later on the Court of Justice gives a very extensive

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[14] Cf KISKA, Roger, p. 5.
[15] Professor of Regenerative Medicine Bioprocessing at University College London
[16] STEM CELL ACTION
[17] Bird & Bird
[18] Eg. Advanced Therapy Medicinal Products Regulation (EC) No 1394/2007 a Tissue and Cell Directive 2004/23/EC
[19] Eg. Oviedo Convention, EU Charter
[20] Article 1 of the Oviedo Convention calls for the protection of human dignity and guarantees to everyone respect for their physical integrity within the context of biology and medicine.
[21] KISKA, Roger, p. 6.
[22] EU Judical Protection: *Lecture of prof. Inge Govaere.*
[23] VO v. France § 38

definition of embryo and in a way decides on the issue when the life begins. Even though these two courts are not formally interconnected, they are both European courts and there has been an informal discussion between them for several years.[24] We therefore wonder what would happen if in the future ECHR was asked to define the point in time when the life begins. Would it once more dare to leave it in the sphere of competences of States?

What we find the most thought-provoking is [up till now theoretical] question, what would happen if the Court of Justice had to decide on preliminary question about the interpretation of legal texts as *Advanced Therapy Medicinal Products Regulation a Tissue and Cell Directive*[25], which among others directly regulate the research on ECS. If the judgment was to stay in the line with the Brüstle argumentation, than in the sense the patent law would in crucial aspects influence other areas of EU law. The question arises whether it really is the aim of the patent law to influence the areas of law which shall directly decide on delicate questions of morality.

One shall bear in mind that we do not seek to judge the effect the judgment may have and to deny that it can be deem positive or negative. One might even claim that in the current situation, when research on ECS causes the destruction on thousands of embryos and the law-makers have not been able to say a definite NO to it by invoking one of the abovementioned documents, than it is right to ban the patenting of the products of the research at least. We however *pose the question*, would not be more appropriate to tackle this question on the forum which was directly created for ascertaining the morality of the research with the aim of regulate it? And would not it be more transparent to apply the agreed approach to the patent law system only when the question has once been solved at this very forum?

There are more questions to cope with. *What if* the regulatory systems allow the research on ECS and *we are deeply persuaded that it is immoral*? Would not it be than right to argue for ban on the patentability of its products at least? To draw a clear distinction, we do not claim, that it is wrong to ban the patentability in this cases. What we claim is, firstly that this kind of ban will not solve the question of morality of research on ECS in the long-term perspective. And secondly, that patent law shall only enshrine how regulatory regimes and thus legitimate authorities decided on related moral questions in the way as the Moon enshrines the light from the Sun. And as well as the Moon is not able to produce the light by its own, the patent law is not in the position primary to say that something is immoral whereas it is allowed and deem as moral by the law of the countries.

Conclusion

We found out that morality firstly occurred in the system of patent law in order to protect society from dangerous inventions, which could not be banned by other means. We learned that it primary purpose was to grand a monopoly right over the invention.

The Court of Justice in the case Brüstle considered the patentability of an invention and consequently banned it on the grounds of morality but simultaneously the research as such remained legal. Based on the arguments and fact presented we are of the opinion that authorities shall limit their decisions on the commercial protection of an invention when deciding within patent law and shall not interfere into the questions of morality. Except for the situations when the invention in question represents the real danger for the society, either direct physical or of its moral foundations, and at the same time there is no authority which could render the invention

[24] EU Judical Protection: *Lecture of prof. Inge Govaere.*
[25] Advanced Therapy Medicinal Products Regulation (EC) No 1394/2007 a Tissue and Cell Directive 2004/23/EC

out of the scope of the moral acceptability and thus illegal. Only when both these conditions are fulfilled, it shall be acceptable that the grant of the patent is denied on the grounds of morality. The direct result of Brüstle decision is merely the situation when nobody can successfully apply for the patent on inventions which presuppose the destruction of embryos in any of its phases but at the very same time thousands of embryos can be legally destroyed and even used for the commercial purposes.

Lastly we deem it necessary to point out that we definitely do not try to defend the viewpoint that technological research shall not underline the moral considerations. We however do argue that moral judgments rendered by EPO and the Court of Justice have greatly overstepped the limit up to which the morality shall interfere into system of patent law. And as a consequence of that the attention in the dispute has been redirected from the morality of the research on ECS as such to the rightness of patentability.

In this regard we find very inspiring what *Charles Taylor once said*: "Instead of seeing it [technical progress] purely in the context of an enterprise of ever-increasing control, of an ever-receding frontier of resistant nature, perhaps animated by a sense of power and freedom, we have to come to understand it as well in the moral frame of the ethic of practical benevolence, which is also one of the sources in our culture from which instrumental reason has acquired its salient importance for us. But we have to place this benevolence in tum in the framework of a proper understanding of human agency, not in relation to the disembodied ghost of disengaged reason, inhabiting an objectified machine. We have to relate technology as well to this very ideal of disengaged reason, but now as an ideal, rather than as a distorted picture of the human essence.[26]

[26] TAYLOR, Charles, p. 106.

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